

all costs and charges arising from inspection and other services provided outside of normal business hours.

§ 301.78–10 Treatments.

Treatment schedules listed in the Plant Protection and Quarantine Treatment Manual to destroy Mediterranean fruit fly are authorized for use on regulated articles. The Plant Protection and Quarantine Treatment Manual is incorporated by reference. For the full identification of this standard, see § 300.1 of this chapter, “Materials incorporated by reference.” The following treatments may be used for the regulated articles indicated:

(a) Fruits and vegetables.

(1) *Bell Pepper*—(i) *Vapor Heat*. Heat by saturated water vapor at 44.4 °C. (112 °F.) until approximate center of bell pepper reaches 44.4 °C. (112 °F.). Maintain at 44.4 °C. (112 °F.) for 8¾ hours, then immediately cool.

(2) *Tomato*—(i) *Fumigation*. Fumigate with methyl bromide at normal atmospheric pressure with 32 g/m³ (2 lb/1000 ft³) for 3½ hours at 21 °C. (70 °F.) or above.

(ii) *Vapor heat*. Heat by saturated water vapor at 44.4 °C. (112 °F.) until approximate center of tomato reaches 44.4 °C. (112 °F.). Maintain at 44.4 °C. (112 °F.) for 8¾ hours, then immediately cool.

NOTE: Commodities should be tested by the shipper to determine each commodity’s tolerance to the treatment before commercial shipments are attempted. The USDA is not liable for damages caused by this quarantine.

(b) *Regulated citrus fruit that has been harvested*. (1) Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m³ (2 pounds per 1000 cubic feet) for 3½ hours at 21 °C. (70 °F.) or above.

NOTE: Some varieties of fruit may be injured by methyl bromide exposure. Shippers should test treat before making commercial shipments.

(2) Fumigation plus refrigeration: Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m³ (2 pounds per 1000 cubic feet) at 21 °C. (70 °F.) or above.

| Fumigation exposure time | Refrigeration |
|--------------------------|---|
| 2 hours | 4 days at 0.55 to 0.7 °C. (33 to 37 °F.); or 11 days at 3.33 to 8.3 °C. (38 to 47 °F.). |
| 2½ hours | 4 days at 1.11 to 4.44 °C. (34 to 40 °F.); or 6 days at 5.0 to 8.33 °C. (41 to 47 °F.); or 10 days at 8.88 to 13.33 °C. (48 to 56 °F.). |
| 3 hours | 3 days at 6.11 to 8.33 °C. (43 to 47 °F.); or 6 days at 9.88 to 13.33 °C. (48 to 56 °F.). |

NOTE: Some varieties of fruit may be injured by methyl bromide exposure. Shippers should test treat before making commercial shipments.

Time lapse between fumigation and start of cooling not to exceed 24 hours. Chamber load not to exceed 80 percent of volume.

(3) Cold treatment: 10 days at 0 °C. (32 °F.) or below; or 11 days at 0.55 °C. (33 °F.) or below; 12 days at 1.11 °C. (34 °F.) or below; 14 days at 1.66 °C. (35 °F.) or below; or 16 days at 2.22 °C. (36 °F.) or below.

(c) *Approved irradiation treatment*. Irradiation, carried out in accordance with the provisions of this paragraph, is approved as a treatment for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.78–2(a) of this subpart.

(1) *Approved facility*. The irradiation treatment facility and treatment protocol must be approved by the Animal and Plant Health Inspection Service. In order to be approved, a facility must:

(i) Be capable of administering a minimum absorbed ionizing radiation dose of 225 Gray (22.5 krad) to the fruits and vegetables;⁸

(ii) Be constructed so as to provide physically separate locations for treated and untreated fruits and vegetables, except that fruits and vegetables traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of car- tons;

(iii) Complete a compliance agreement with the Animal and Plant

⁸The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.

Health Inspection Service as provided in § 301.78-6 of this subpart; and

(iv) Be certified by Plant Protection and Quarantine for initial use and annually for subsequent use. Recertification is required in the event that an increase or decrease in radioisotope or a major modification to equipment that affects the delivered dose. Recertification may be required in cases where a significant variance in dose delivery is indicated.

(2) *Treatment monitoring.* Treatment must be carried out under the monitoring of an inspector. This monitoring must include inspection of treatment records and unannounced inspection visits to the facility by an inspector. Facilities that carry out continual irradiation operations must notify an inspector at least 24 hours before the date of operations. Facilities that carry out periodic irradiation operations must notify an inspector of scheduled operations at least 24 hours before scheduled operations.⁹

(3) *Packaging.* Fruits and vegetables that are treated within a quarantined area must be packaged in the following manner:

(i) The cartons must have no openings that will allow the entry of fruit flies and must be sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.¹⁰

(ii) The pallet-load of cartons must be wrapped before it leaves the irradiation facility in one of the following ways:

- (A) With polyethylene sheet wrap;
- (B) With net wrapping; or
- (C) With strapping so that each carton on an outside row of the pallet load

is constrained by a metal or plastic strap.

(iii) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(4) *Dosage.* The fruits and vegetables must receive a minimum absorbed ionizing radiation dose of 225 Gray (22.5 krad).¹¹

(5) *Dosimetry systems.* (i) Dosimetry must demonstrate that the absorbed dose, including areas of minimum and maximum dose, is mapped, controlled, and recorded.

(ii) Absorbed dose must be measured using a dosimetry system that can accurately measure an adsorbed dose of 225 Gray (22.5 krad).

(iii) The utilization of the dosimetry system, including its calibration and the number and placement of dosimeters used, must be in accordance with the American Society for Testing and Materials (ASTM) standards.¹²

(6) *Records.* Records or invoices for each treated lot must be made available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). An irradiation processor must maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, and must make these records available for inspection by an inspector. These records must include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(7) *Request for approval and inspection of facility.* Persons requesting approval of an irradiation treatment facility and treatment protocol must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565.

⁹Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

¹⁰If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565.

¹¹See footnote 8.

¹²Designation E 1261, "Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing," American Society for Testing and Materials, Annual Book of ASTM Standards.

Before the Administrator determines whether an irradiation facility is eligible for approval, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of paragraph (c)(1) of this section.

(8) *Denial and withdrawal of approval.*

(i) The Administrator will withdraw the approval of any irradiation treatment facility when the irradiation processor requests in writing the withdrawal of approval.

(ii) The Administrator will deny or withdraw approval of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying approval, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend approval pending final determination in the proceeding, if he or she determines that suspension is necessary to prevent the spread of any dangerous insect infestation. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

(9) *Department not responsible for damage.* This treatment is approved to assure quarantine security against Mediterranean fruit fly. From the literature available, the fruits and vegetables authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator and shipper are responsible for determination of tolerance. The Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from any treatment prescribed or supervised. Additionally, the Nuclear Regulatory Commission is

responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption.

(d) *Premises.* A field, grove, or area that is located within the quarantined area but outside the infested core area, and that produces regulated articles, must receive regular treatments with malathion bait spray. These treatments must take place at 6 to 10-day intervals, starting a sufficient time before harvest (but not less than 30 days before harvest) to allow for completion of egg and larvae development of the Mediterranean fruit fly. Determination of the time period must be based on day degrees. Once treatment has begun, it must continue through the harvest period. The malathion bait spray treatment must be applied at a rate of 1.2 fluid ounces of technical grade malathion (1.4 ounces by weight) and 10.8 fluid ounces of protein hydrolysate (13.2 ounces by weight) per acre, for a total of 12 fluid ounces per acre.

(e) *Soil.* Soil within the drip area of plants that are producing or have produced the berries, fruits, nuts, and vegetables listed in §301.78-2(a) of this subpart: Apply diazinon at the rate of 5 pounds actual ingredient per acre to the soil within the drip area with sufficient water to wet the soil to a depth of at least ½ inch. Both immersion and pour-on treatment procedures are also acceptable.

(Approved by the Office of Management and Budget under control number 0579-0088)

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Subpart—Witchweed

QUARANTINE AND REGULATIONS

§ 301.80 Quarantine; restriction on interstate movement of specified regulated articles.

(a) *Notice of quarantine.* Pursuant to the provisions of sections 8 and 9 of the Plant Quarantine Act of August 20, 1912, as amended, and section 106 of the